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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,908	12/15/2000	Jason Hill	C059US	2440
34103	7590	10/17/2006	EXAMINER	
CUBIST PHARMACEUTICALS, INC. 65 HAYDEN AVENUE LEXINGTON, MA 02421			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/737,908

Applicant(s)

HILL ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 3, 8, 27 and 31 is/are rejected.
- 7) ☒ Claim(s) 5-7, 9-26 and 28-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the directives of the response filed 7/27/06, several claims have been amended, and claims 32-33 added. Claims 3-33 are now pending.

The previously non-elected claims are now rejoined with the elected claims. Claim 4 remains allowable; claims 3, 8, 27, 31 are now rejected, and claims 5-7, 9-26, 28-30 are objected to because of their dependence on rejected claims.

Applicants' arguments filed 7/27/06 have been considered and found persuasive in part.

The §102(b) rejection over Abbot ('717) is withdrawn.



Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending application Serial No. 11/121851. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the respective genera. Applicants have requested that the rejection be reconsidered, but have offered no reason as to why it might be improper. Accordingly, the rejection is maintained.



The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 31 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The issue here is how to “make” many of the compounds of claim 3. For example, if the “target” compound is one in which variable A is alkyl, alkenyl, alkynyl or aryl, and “n” is zero, the specification does not teach how to accomplish this using the reagents that are listed in claim 31.

Or suppose that the objective is to synthesize a compound in which R¹⁶ is lysine, and wherein R¹⁵ is an amino protecting group. How would applicants propose to accomplish this if the starting material were a compound of claim 29 in which R¹⁵ is hydrogen?

Accordingly, “undue experimentation” would be required to practice the claimed invention.



Claims 3, 8, 27, 31 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 3 recites several provisos that pertain to (X')_m-A'. One of these is listed as

“(f)”, where the following is recited:

“-C(O)C₁-C₁₈ selected substituted alkyl... is replaced by a halo substituents”.

There are two minor issues. First, the word “selected” appears to be out of place, and second, there is a minor grammatical error in the following phrase: “a halo substituents”.

- Claim 8 recites that R¹ can be -NH-CH₂-R¹², and that R¹² can be unsubstituted alkyl. Claim 3, upon which claim 8 depends, recites that when R¹ is -NH-A', substituent variable A' cannot be C₄-C₁₄ unsubstituted alkyl. Thus, there is a contradiction. Which limitation controls?
- In claim 27, line 2, it appears that a preposition might be missing.
- In claim 31, variable R¹⁶ is not defined. One might infer that applicants intend for the definition presented in claim 29 to apply, but if intended, this should be made clear. Similarly, the following phrase should be added to claim 31:

wherein R is as defined in claim 3.

- With respect to claim 31, suppose that the objective is to make the compound in which R is -NH₂. If one starts with the compound of claim 29 in which R¹⁵ is hydrogen, one is starting with the compound that one wants to synthesize. What process steps would one undertake in such a situation?



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER